

IN THE CIRCUIT COURT, FOURTH
JUDICIAL CIRCUIT, IN AND FOR
DUVAL COUNTY, FLORIDA

CASE NO.: 2019-CA-2876

DIVISION: CV-C

CATHERINE BIANCHI,

Plaintiff,

v.

**MARK A. CLAYMAN, M.D.,
LOREN Z. CLAYMAN, M.D., P.A.,
a Florida corporation,
ELANA CLAYMAN, and
ALLERGAN SALES, LLC,
a foreign limited liability company,**

Defendants.

COMPLAINT

The Plaintiff, **CATHERINE BIANCHI**, sues the Defendants, **MARK A. CLAYMAN, M.D., LOREN Z. CLAYMAN, M.D., P.A., ELANA CLAYMAN, and ALLERGAN SALES, LLC**, and alleges the following:

GENERAL ALLEGATIONS

1. This is an action for damages in excess of \$15,000, exclusive of attorney's fees, costs, and interest.
2. All conditions precedent to the filing of this action have been performed or have occurred.
3. At all times material hereto, the Plaintiff, **CATHERINE BIANCHI** (hereinafter "Ms. Bianchi"), was and is a resident of, and permanently domiciled in, Jacksonville, Duval County, Florida.

4. All medical care and treatment rendered to Ms. Bianchi upon which the claims set forth herein are based took place in Jacksonville, Duval County, Florida.

5. At all times material hereto, the Defendants, **MARK A. CLAYMAN, M.D.** (hereinafter “Clayman Junior”) and **ELANA CLAYMAN**, were and are residents of, and permanently domiciled in, Jacksonville, Duval County, Florida.

6. At all times material hereto, the Defendant, **LOREN Z. CLAYMAN, M.D., P.A.** (hereinafter “the Clayman Practice”) was and is a Florida Corporation, existing and operating under the laws of the State of Florida, and in fact doing business in Jacksonville, Duval County, Florida, to-wit: offering plastic surgery and aesthetic spa services and products to the general public. The Clayman Practice’s principal address is 1801 Barrs Street, Suite 200, Jacksonville, Florida 32204, and the Clayman Practice may be reached for service of process through its registered agent, Loren Z. Clayman, M.D. (hereinafter “Clayman Senior”), at 1801 Barrst Street, Suite 200, Jacksonville, Florida 32204.

7. The Defendant **ALLERGAN SALES, LLC** (hereinafter “Allergan”) was and is a foreign limited liability company, with its principal place of business and permanent domicile at 2525 Dupont Drive, Irvine, California 92612.

8. Allergan is authorized to do business in the State of Florida, and has and is doing business in the State of Florida, to-wit: researching, testing, designing, developing, manufacturing, marketing, promoting, distributing, selling, or otherwise placing into the stream of commerce medical devices and/or pharmaceuticals, including but not limited to, Allergan Natrelle saline filled breast implants and warranties for same, in Jacksonville, Duval County, Florida.

9. Allergan may be reached for service of process in Florida through its registered agent, CT Corp. System, at 1200 South Pine Island Road, Plantation, Florida 33324.

10. Allergan's co-conspirators and joint venturers, whom Allergan aided and abetted in a fraudulent scheme, were: (i). Clayman Senior"); (ii). Clayman Junior; (iii). Clayman Senior's wife, Elana Clayman (hereinafter "Elana Clayman") and (iv). the Clayman Practice.

FACTUAL ALLEGATIONS

The Clayman Saline Breast Implant Warranty Scheme

11. Clayman Senior was first licensed as a medical doctor in the State of Florida on January 10, 1975. On December 31, 1976, he completed a residency in plastic surgery, and he began practicing in Jacksonville, Florida. Soon after establishing his plastic surgery practice at the P.A., he began performing breast augmentation surgeries. During the 1980's, a substantial portion of the breast augmentation procedures he performed were with silicone filled breast implants.

12. After the FDA prohibited the sale of most silicone implants in 1992, Clayman Senior began using saline filled implants exclusively.

13. As of the early 2000s, the Clayman Practice began marketing its breast augmentation practice to patients of modest means. To reach this population of potential patients, the Clayman Practice advertised extensively in free local discount publications such as *Mint Magazine*, *Money Pages*, and *Folio Weekly*; samples of these advertisements are attached and incorporated by reference as "Composite Exhibit A."

14. To attract patients of modest means, the Clayman Practice began charging less than any other plastic surgeons for augmentation mammoplasty procedures. Specifically, the Clayman Practice charged no more than \$3,750 for an augmentation mammoplasty procedure

(breast augmentation); by contrast, most plastic surgeons in the Jacksonville, Florida community charged between \$5,000 and \$10,000 for a breast augmentation.

15. To reach this very low price point, the Clayman Practice did the following: performed procedures within its own offices rather than at a hospital or surgical center; performed procedures without the assistance of an anesthesiologist or qualified nurse anesthetist; set up two surgical rooms connected by a swinging door, so the surgeon could have two surgeries going at one time; performed breast augmentations in only 20 to 30 minutes, when most plastic surgeons take between one and two hours; purchased saline solution in large bulk bottles rather than single use surgical bags; and used the same make and model saline breast implant for every procedure because it was the cheapest. Indeed, after the FDA once again permitted silicone breast implants for breast augmentations, the Clayman Practice continued using saline breast implants exclusively because they were cheaper than silicone implants.

16. No later than the mid-2000s, Clayman Senior and/or Elana Clayman began repeatedly telling their breast augmentation patients that they had ruptured, deflated, or leaking saline breast implants, and that they needed to have removal and replacement surgeries as a result. However, Clayman Senior and/or Elana Clayman were lying to their patients; the breast implants were not ruptured, deflated, or leaking (not defective); and the removal and replacement surgeries they recommended were not necessary. Clayman Senior and/or Elana Clayman lied to their patients because they knew that most of them could not afford to pay for additional surgeries, but that by claiming that saline breast implants were ruptured, deflated, or leaking, they could seek to have the breast implant manufacturers pay for additional surgeries through their Warranties. After June 30, 2008, Clayman Junior joined the Clayman Practice and began practicing plastic surgery, including breast augmentations. He, too, began lying to his patients

about ruptured, deflated, or leaking saline breast implants, and he also began making an excessive or unusually high number of warranty claims for saline breast implants.

17. To make false warranty claims to Inamed/McGhan (which was later acquired by Allergan), the Clayman Practice and/or Elana Clayman had each patient and Clayman Senior or Junior sign a warranty claim form stating that the patient had a rupture, deflation, or leak that required a removal and replacement surgery, and assigning the benefits of the warranty to the Clayman Practice. The Clayman Practice and/or Elana Clayman had patients sign Allergan's claim forms *before* the surgeon had even performed the removal and replacement surgery to confirm that a rupture, deflation or leak had actually occurred. After the surgery, the Clayman Practice and/or Elana Clayman sent the completed warranty claim form and removed saline implant(s) to Allergan pursuant to the requirements of the Warranty.

18. Upon receiving the warranty claim paperwork and the returned breast implant(s) from the Clayman Practice and/or Elana Clayman, Allergan would then undertake a "Laboratory Analysis" on the returned breast implants to determine the cause of a claimed rupture/deflation/leak; after making the determination, Allergan generated a report of its findings.¹ Nearly every *Laboratory Analysis* report for saline filled breast implants returned by the Clayman Practice and/or Elana Clayman found no evidence of a "loss of shell integrity, resulting in implant rupture or deflation." Nevertheless, Allergan sent the Clayman Practice a check for the Surgery Money (either \$1,200 or \$2,400, depending upon the type of Warranty that applied) for every warranty claim made by the Clayman Practice over a 15-year period. As a result, Allergan funded thousands of harmful, unnecessary surgeries procured by the Clayman Practice's lies to patients.

¹ One important reason the Clayman-Allergan scheme was undiscovered for a number of years was that Allergan did not as a matter of course provide patients with copies of their *Laboratory Analysis* reports.

19. From the *Laboratory Analysis* reports and the claim forms--signed jointly by Clayman Senior or Junior and each patient—Allergan knew two facts: First, Allergan knew that the Clayman Practice was lying to its patients about their need for unnecessary removal and replacement surgeries; second, Allergan knew that these lies were made for the purpose of procuring from Allergan, through the Warranty, the Surgery Money. In particular, the claim forms, signed by Clayman Senior or Junior and the patients, revealed to Allergan that Clayman Senior or Junior had told patients their implants were ruptured, deflated or leaking and needed to be surgically removed and replaced; the corresponding *Laboratory Analysis* reports, however, demonstrated to Allergan that Clayman Senior or Junior's representations to patients were false and intended to procure the Surgery Money for unnecessary removal and replacement surgeries. Armed with this knowledge, Allergan could have refused to pay the Surgery Money under the terms of the Warranty. Instead, Allergan paid the Surgery money to the Clayman Practice so that the Clayman Practice could "pocket" the Surgery Money for unnecessary removal and replacement surgeries.

20. When Clayman Senior and Elana Clayman first began pursuing the saline breast implant warranty scheme in the mid-2000s, the Clayman Practice purchased saline filled breast implants from both Allergan and Mentor, Allergan's primary American competitor in the manufacture of breast implants (Mentor was later acquired by Johnson & Johnson). When Mentor received a high number of warranty claims relative to the number of implants purchased by the Clayman Practice, Mentor's quality assurance department (hereinafter "Mentor QA") contacted its regional sales manager and advised him that the Clayman Practice had made approximately 40 warranty claims in the preceding year, which amounted to 30% of all saline breast implants the Clayman Practice purchased from Mentor. Mentor QA considered this

percentage to be excessive and indicative of fraud. Mentor QA asked its regional sales manager to visit the Clayman Practice in person and demand an explanation for the excessive number of saline breast implant warranty claims.

21. Thereafter, the regional sales manager went to the Clayman Practice and told a female employee that he needed to discuss the excessive saline breast implant warranty claims with Clayman Senior. In response, the employee said, “I told him he was going to get in trouble if he kept doing this.” When the employee went to Clayman Senior’s office to tell him that the regional sales manager wanted to speak with him, she returned soon afterward and told the regional sales manager that Clayman Senior did not wish to speak with him. In response, the regional sales manager told the employee that Mentor would no longer sell breast implants to the Clayman Practice. Since this incident, Allergan has been the exclusive supplier of breast implants to the Clayman Practice.

22. In contrast to Mentor, Allergan has never confronted Clayman Senior about his excessive warranty claims for saline breast implants, even as the number of warranty claims to Allergan has increased exponentially. A copy of a bar graph showing the Clayman Practice’s saline breast implant warranty claims to Allergan between January 1, 2000 and December 31, 2015 is attached and incorporated by reference as “Exhibit B” to this *Complaint*.

23. According to Allergan’s own studies, the rate of spontaneous deflations for Natrelle saline filled breast implants is approximately 2.7% to 6.8% at 5 years, and approximately 10% to 13.8% at 10 years, which amounts to an average deflation rate of 1.2% for each year after implantation.

24. By comparison, between January 1, 2008 and December 31, 2015, Allergan sold the Clayman Practice **11,082** pairs of saline breast implants. During that same time period, the

Clayman Practice made **5,118 warranty** claims for saline breast implants, which amounts to a **failure rate of 46%**.

25. Allergan had a deep financial motivation for paying the Clayman Practice's 5,118 warranty claims. Between January 1, 2008 and December 31, 2015, the Clayman Practice purchased 11,082 pairs of saline breast implants from Allergan, which makes the Clayman Practice one of Allergan's top 10 breast implant customers in Florida. Furthermore, the Clayman Practice purchased a host of other aesthetic products from Allergan, including the following: Botox, Latisse, Juvederm, Kybella, SkinMedica, Vivate, and CoolSculpting (a product marketed by Zeltiq Aesthetics, which is a subsidiary of Allergan). As the above-noted print advertisements from the Clayman Practice show ("Composite Exhibit A"), the Clayman Practice is essentially a "one supplier shop."

26. The Clayman Practice is a Diamond Level member of the Allergan Partner Privileges program for Allergan Aesthetics products (i.e., Natrelle, Botox, Latisse, Juvederm, Kybella, SkinMedica, Vivate, and CoolSculpting). The Allergan Partner Privileges program provides members with rebates, sales growth rewards, a special online physician locator listing, priority customer service line access, preferred shipment status, and certificates and status displays.² Indeed, when a nurse employed by the Clayman Practice asked Clayman Senior why he believed Allergan would keep paying his high volume of warranty claims without question, Clayman Senior told her, "I know they're going to pay them all because I'm a Diamond Level partner."

27. Hence, even though Allergan knew that the Clayman Practice was lying to its patients about leaking, ruptured or deflated implants, that the Clayman Practice was performing

² See, <https://www.allergannetwork.com/components/app/content/pdf/APP2.0-Customer-FAQ.pdf>.

unnecessary removal and replacement surgeries, and that the Clayman Practice was making false warranty claims for its saline breast implants, Allergan paid millions of dollars in false warranty claims to the Clayman Practice because it was making so much money in total sales of aesthetic products from the Clayman Practice.

28. Other plastic surgeons report that in response to their saline breast implant warranty claims, Allergan demanded further proof that the claimed ruptures, deflations, or leaks were not the result of actions by patients or surgeons, even though the other plastic surgeons made fewer than 5 saline breast implant warranty claims per year. Oftentimes, the other plastic surgeons' warranty claims were ultimately denied by Allergan. The key distinction between these other plastic surgeons and the Clayman Practice is that the other plastic surgeons were not "one supplier shops," and they purchased their aesthetic products (including saline breast implants) from more than one supplier.

**Allergan's Warranty through which Allergan Knowingly Funded
the Clayman Practice's Unnecessary, Harmful Surgeries**

29. With all Natrelle breast implants, Allergan includes its "ConfidencePlus Warranty." According to its own literature, Allergan's Warranty applies to all FDA-approved Natrelle breast implants, provided the implants were used as intended and as directed, by qualified and licensed surgeons. However, the Warranty only applies to cases of:

- Loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention
- Capsular contracture (Baker Grade III/IV) with *Natrelle* Gel implants that requires surgical intervention

30. There are two versions of the Warranty: Standard and Premier. The Premier Warranty costs an additional \$100 with each newly purchased pair of implants, and \$200 after a

replacement under the Warranty; the Standard Warranty comes at no additional cost with each newly purchased pair of implants, but costs an additional \$100 after a replacement under the Warranty. The Standard Warranty provides, among other things, for a lifetime replacement of the ruptured implant and, for ten years, the replacement of the contralateral implant.³ The Premier Warranty provides, among other things, for lifetime replacement of both ruptured and contralateral implants. The Standard Warranty initially comes with Natrelle implants free of additional cost, and costs \$100 in the event of revision surgeries under warranty.

31. For purposes of this case, the critical coverage under both Warranties was the amount reimbursed for the cost of replacement/revision surgery (the “Surgery Money”). Under the Standard Warranty, if the originally provided implants were ruptured or otherwise deemed defective under the Warranty, then Allergan would not only provide replacement implants, but it would also provide \$1,200 of Surgery Money for the cost of removing and replacing the patient’s implants. Under the Premier Warranty, Allergan provided \$2,400 of Surgery Money for the cost of replacement/revision surgery.

32. In relation to patients of the Clayman Practice, the Surgery Money provided by Allergan went not to the patient who purchased the Warranty, but to the surgeon performing the removal and replacement surgery, i.e. the Clayman Practice. In Ms. Bianchi’s case, and the cases of the Clayman Practice’s other breast augmentation patients, the surgeons at the Clayman Practice pocketed the Surgery Money, which was funneled through Allergan’s Warranty, and used the Surgery Money to perform thousands of unnecessary surgeries that harmed their patients. The surgeons at the Clayman Practice and Elana Clayman repeatedly lied to their

³ At first, only Natrelle Style 163 saline filled implants had lifetime replacement for contralateral breast implants; other Natrelle saline filled implants had only a 10 year warranty for contralateral implants. Beginning June 1, 2009, the Standard warranty was changed to provide for the lifetime replacement of contralateral breast implants for all Natrelle saline filled implants.

patients, including Ms. Bianchi, telling them that the original implants were ruptured, deflated, or leaking and that, as a result, they needed surgery to remove and replace their purportedly defective saline breast implants. Allergan knew about these lies, and the company substantially assisted, conspired with, and engaged in a joint venture with the surgeons' fraudulent scheme by funding the unnecessary, harmful surgeries by directly paying the Surgery Money to the Clayman Practice and/or Elana Clayman.

33. Since acquiring McGhan/Inamed, Allergan devised an "off-balance-sheet" method of paying warranty claims for Natrelle saline filled breast implants. Specifically, to the best of the undersigned attorney's information and belief, Allergan pays breast implant warranty claims through Del Mar Indemnity Company, LLC, a captive insurance company created and owned by Allergan.⁴ When a manufacturer such as Allergan creates a captive insurance company, the manufacturer is provided a means of reclassifying otherwise taxable income from across its various divisions and subsidiaries as "premium payments" that go to the captive insurance company. The formerly taxable income that is reclassified as "premiums" then accumulates within the captive, making it, essentially, a very large "slush fund." In the event that the manufacturer uses the captive insurance company to pay a "loss," such as a warranty payment, the loss is not reflected in Allergan's balance sheets or filings with the Securities and Exchange Commission. In addition, because the captive is not a third-party company, Allergan is free to manipulate the claims payment process without outside interference.

**Allergan's Similar Course of Conduct during the Same Period of Time
in which the Company Paid Physicians to Use Their Products**

34. The Clayman saline implant warranty scheme is not the first time Allergan has

⁴ See, https://opencorporates.com/companies/us_hi/206243D1.

been implicated in a scheme whereby the company bribes physicians to purchase the company's products, as Allergan has been implicated in violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), at least six times, resulting in Allergan paying a total of \$1.089 billion in criminal penalties and civil settlements.

35. The Anti-Kickback Statute prohibits anyone from

knowingly and willfully offer[ing] or pay[ing] remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

...

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program⁵...

42 U.S.C. §1320a-7b(b)(2).

36. Over the past eight years, Allergan was involved in the following:

A. **September 1, 2010**, Allergan was forced to pay \$600 million in settlement of criminal and civil complaints that included allegations of providing free physician workshops and dinners, paying physicians to attend “advisory boards” promoting off-label uses, and created Alphamedica, which administered a speakers bureau that paid physicians \$1,000 to allow sales representatives to shadow them at work.⁶

⁵ Because the Clayman Practice's patients paid for their breast augmentation procedures with cash (not under a Federal health care program), the Anti-Kickback Statute does not apply to the Clayman scheme, and Plaintiff asserts no claim under the Anti-Kickback Statute. Plaintiff, however, alleges the facts concerning Allergan's conduct under the Anti-Kickback Statute to show this Court that it is quite plausible that Allergan, consistent with its past criminal conduct, engaged here in criminal conduct by conspiring with, substantially assisting, and jointly venturing with the Clayman Practice to perpetuate fraud upon its patients.

⁶ See, <https://www.justice.gov/opa/pr/allergan-agrees-plead-guilty-and-pay-600-million-resolve-allegations-label-promotion-botox>; <https://www.cbsnews.com/news/how-allergan-sponsored-a-history-of-sausages-to-promote-botox-illegally/>.

B. **September 15, 2010**, Allergan's Forest Laboratories division was forced to pay a \$313 million settlement of criminal and civil complaints that included allegations of cash payments to physicians that the company described as "grants" and "consulting fees," expensive meals, and lavish entertainment to physicians to induce them to prescribe the drugs Celexa and Lexapro.⁷

C. **October 29, 2015**, Allergan's Warner Chilcott division was forced to pay a \$125 million settlement in a case that included allegations of violations of paying doctors speaking fees to induce them to prescribe the drugs Asacol, Actonel, and Loestrin.⁸

D. **December 15, 2016**, Allergan's Forest Laboratories division was forced to pay a \$38 million settlement in a case that included allegations of paying kickbacks to physicians to induce them to prescribe the drugs Bystolic, Savella, and Namenda.⁹

E. **June 29, 2017**, Allergan was forced to pay a \$13 million settlement in a case involving allegations of providing valuable business consulting services, continuing medical education, and other valuable services to physicians to induce them to prescribe Allergan eye care products including Restasis, when other less expensive treatment alternatives were available.¹⁰

⁷ See, <https://www.justice.gov/opa/pr/drug-maker-forest-pleads-guilty-pay-more-313-million-resolve-criminal-charges-and-false>.

⁸ See, <https://www.wsj.com/articles/allergan-unit-to-plead-guilty-to-fraud-pay-125-million-1446139657/?mod=mktw>.

⁹ See, <https://www.justice.gov/opa/pr/forest-laboratories-and-forest-pharmaceuticals-pay-38-million-resolve-kickback-allegations>.

¹⁰ See, http://www.pietragallo.com/library/files/nevyas_allergan_press_release_final.pdf.

F. **Pending case, *U.S. ex rel. Wood v. Allergan, Inc.***, civil complaint includes allegations that Allergan provided “customer care kits,” office supplies, and over \$100 million in free drug samples to targeted physicians to induce them to prescribe Allergan drugs.¹¹

37. Allergan’s previous conduct demonstrates that its involvement in the Clayman breast implant warranty scheme was and is part of a larger course of conduct whereby the company’s marketing plan includes bribing physicians.

Catherine Bianchi

38. In October of 1998 Ms. Bianchi underwent a mastopexy procedure by a plastic surgeon. Because her breasts were still sagging after this procedure, she returned to the surgeon with additional complaints of sagging, and in January of 1999, the surgeon performed a “nipple lift” bilaterally. In August of 1999, Ms. Bianchi presented to a different plastic surgeon with complaints that her breasts were still sagging, and the new plastic surgeon recommended a breast augmentation, which she underwent that same month. In December of 1999, she returned to the plastic surgeon with complaints that her left breast was larger than her right breast. Accordingly, in December of 1999, the second plastic surgeon performed a revision surgery that corrected the asymmetry, leaving her breasts inflated bilaterally to 275cc.

39. In November of 2013, Ms. Bianchi experienced a rupture of the saline implant in her left breast. In response, on November 19, 2013 she presented to Clayman Junior for a consultation. During the consultation, she told Clayman Junior that she wanted her implants removed and replaced bilaterally so that her breasts would again be 275cc bilaterally. Clayman Junior performed a very brief physical examination without taking any measurements. After the

¹¹ See, 246 F.Supp.3d 772 (S.D. N.Y. March 31, 2017).

examination, he diagnosed her as having experienced a deflation of her left breast implant, and he recommended that she undergo a removal and replacement procedure bilaterally along with an “internal lift.” Although Clayman Junior documented in his first operative note that the patient refused mastopexy scars, Ms. Bianchi states that a mastopexy was never discussed during her first visit with him. He also told her that if she was unhappy with the size of her breasts within 6 to 8 months after surgery, he would perform a revision procedure at no charge to her. He told her that normally he would charge her \$7,200 for all of the recommended procedures, but that he would perform them for the “special” price of \$3,750. Clayman Junior then provided her with a written surgical estimate that outlined his plan for her breasts, and the charges she would incur. In fact, at the time Clayman Senior and Clayman Junior almost universally charged women \$3,750 for breast augmentation surgeries. In addition, Ms. Bianchi paid for Allergan’s warranty for this surgery.

40. On December 9, 2013, Ms. Bianchi presented to the Clayman Practice for the recommended surgery. At that time, she wrote in her surgical intake forms that she wanted Clayman Senior to “try to get rid of the flat spot on [her] Right breast.” She also reported having “very little feeling” in her breasts. Lastly, she wrote that she wanted him to “[r]emove the stitch that was left in from before.” Ms. Bianchi wrote that she wore a 34D bra, and that she wanted her breasts to be the same size after Clayman Junior’s surgery. An employee of the Clayman Practice then took a single AP photograph of her breasts, as well as a single close up photograph of her left breast (which was very blurry). These photographs show asymmetry with the left breast slightly smaller, and flattening of the right breast with an indentation near the nipple/areola complex. The breasts have an obviously augmented look without natural shape. Clayman Practice employees had Ms. Bianchi sign a surgical consent form that stated she would

be undergoing a bilateral removal and replacement procedure with saline implants, as well as an “internal lift.”

41. According to the operative report of December 9, 2013, Ms. Bianchi underwent “Bilateral Re-augmentation saline implant” and “Bilateral internal lift.” The operative report mentions a “pectus asymmetry to the chest and rib asymmetries” which are not obvious in any photographs of the patient, and which the patient denies having.¹² After making an incision around her areola, Clayman Junior dissected down to the left implant capsule, removed it, and documented that it “had a deflation with almost complete loss of volume from the implant.” Upon dissection, the right implant was found to be intact. Both implants were removed and replaced with 400cc Allergan Natrelle Style 68 High Profile saline breast implants bilaterally. Clayman Junior failed to document how much saline he used to inflate the implants; instead, he merely documented that they were “inflated to their optimal capacity to minimize rippling and give the patient her desired look with as much symmetry as possible without added mastopexy scars.” Clayman Junior documented using nylon sutures to adjust for the differences in the capsules, and to “internally support the breasts higher and closer on the chest wall.” According to the OR Record, the entire procedure took 86 minutes to complete.

42. After the surgery, Ms. Bianchi realized that Clayman Junior made her breasts much larger despite her explicit request that her breasts remain the same size. Beginning immediately after the surgery, she also began having persistent pain at the sites of the “internal lift.” She returned for a follow up visit on December 11, 2013, at which time she complained about the size of her breasts. In response, Clayman Junior told her “not to worry,” and that her

¹² Before this surgery, no physician ever told her that she had any sort of chest wall deformity. After she stopped seeing Clayman Junior, her *subsequent* plastic surgeon told her Clayman Junior caused the deformity when he placed overfilled saline implants in her chest, which created the deformity by pushing her ribs inward.

breasts would “be fine.” He also told her that during the procedure he sewed the sides of her breasts to give her more “cleavage,” and that she would “would love them.”

43. Ms. Bianchi had additional post-surgical follow up visits with Clayman Junior on December 16, 2013, and December 26, 2013; Clayman Junior failed to document any physical examinations or patient complaints for these visits, although his treatment ledger notes her complaining of a blister on her left breast, that lidocaine tape was applied, and that sutures were removed. According to Ms. Bianchi, she repeatedly complained to Clayman Junior that she was unhappy with the size and shape of her breasts, especially at the left breast, which was “starting to deform” and cause discomfort. She had repeated complaints of pain that Clayman Junior seemed to ignore. Eventually, she sent him a letter with her complaints, but the Clayman Junior and the Clayman Practice failed to incorporate the letter into her patient records. According to the follow up ledger, on January 6, 2014, Clayman Junior injected her with B-12, and also repaired her right breast incision; there is no operative report for right incision repair procedure.

44. On November 6, 2014, Ms. Bianchi returned to Clayman Junior with complaints that her left breast was tender and a different size compared to her right breast. She reported that a co-worker elbowed her in the left breast while working at Starbucks. Clayman Junior told Ms. Bianchi she probably had a deflation at her left implant, and that he needed to perform a bilateral removal and replacement procedure. She asked him to make her breasts smaller (only 275cc), the size she had asked him to make them before his first surgery. In the patient chart, Clayman Junior included a hand-written note for this date that says:

Tenderness to chest at work [indecipherable]. Now noticing size Diff. b/w Breast.
Exam: [indecipherable] Ecchymosis Breast [left] inf/Lat. Aspect. Tender LSR.
-Poss. Just swelling vs. leak from Trauma. Bothers PT. Risk of [capsular contracture] [indecipherable]. Pt Think injured implants. Will Watch & Plan to

explore & correct Asym. If leak Present, will replace. Conserv. Tx. For [capsular contracture; revise when swelling subsides.

45. On November 21, 2014, Ms. Bianchi presented to the office of the Clayman Practice for her second breast surgery with Clayman Junior. In the surgical intake paperwork, she wrote that her left breast was smaller than her right breast, and that both breasts were sagging. Before the procedure, Clayman Practice personnel had her sign an informed consent document that stated she had a “possible left deflation,” and that she would be receiving a “Bilateral Adjustment” or “Replacement.” Ms. Bianchi was presented with blank forms to sign, and the staff told her they would complete the forms later. She was never aware that she was signing an implant manufacturer’s warranty application that attested to her having experienced a rupture, leak or deflation. A preoperative AP photograph taken that same date by Clayman Practice’s staff demonstrates asymmetry, with the left breast smaller than the right; the right implant appears grossly overfilled.

46. In the operative report dated November 21, 2014, Clayman Junior documented dissecting down to the left breast implant capsule, which was found to have a “partial deflation with leak at the valve.” The right breast implant was found to be intact. Both implants were removed and replaced with Allergan Natrelle Style 68 High Profile 425cc saline breast implants. Clayman Junior failed to document how much saline he used to inflate the implants, other than they were “inflated to their optimal capacity to minimize rippling and give the patient the desired look with as much symmetry as possible without added scars.” He also documented adjusting both implant capsules with nylon sutures “for the differences, and to internally support the breasts.” According to the OR Record, the entire procedure took 63 minutes to complete.

47. Pursuant to the terms of the Allergan breast implant warranty program, Clayman Junior sent the removed implants and completed claim form to Allergan. Thereafter, Allergan

sent the Clayman Practice a check for \$1,200 in relation to the implants removed on November 21, 2014. Elana Clayman deposited the surgery money received from Allergan into a separate bank account.

48. On November 21, 2014, Clayman Junior sent Ms. Bianchi's employer a note stating that his surgery was "work related."

49. According to Ms. Bianchi, after the surgery she complained to Clayman Junior that her breasts were too big and painful; in response, Clayman Junior told her not to worry, and that she would "love them." Thereafter, she had pain at her left and right sides, her breasts felt as if they were about to burst, she had a dimple on her left breast, and she had an indentation on her right breast. Her persistent complaints of pain went on ignored by Clayman Junior.

50. On February 9, 2015, Ms. Bianchi returned to Clayman Junior and reported that she was in "a lot of pain," and that she wanted her implants to be smaller. Although nothing is documented in the follow-up/consult note for this visit, Clayman Junior attached a hand-written note to the chart that stated:

-Pt return to [indcipherable] to Dec. vol has seen some recurrent changes to breast, R>L. Denies Trauma or injury but Exam shows some resolving ecchymosis to Both Breasts. Good symmetry several months Back before Christmas, [complains of] New changes.

Clayman Junior told her that he planned to decrease the volume of her breast implants, but that they would wait two months to see if she had any changes to her breasts.

51. On February 9, 2015, Clayman Junior provided Ms. Bianchi with a surgical estimate stating that she would undergo a procedure in which she would receive a "decrease size" of her breast implants at no charge to her.

52. On April 30, 2015, Ms. Bianchi presented to the Clayman Practice for her third breast surgery with Clayman Junior. In the surgical intake paperwork, she wrote her breasts

were too large, and that she wanted them to be a size D. She did not have complaints of deflation at this time. She reported that her right breast had a “hard spot on upper, inner side, hurts often.” She also complained that her left breast appears to be sagging “much more.” She further wrote that her bra size was 32F and that she wanted to be 32D. Before the procedure, Clayman Practice personnel had her sign an informed consent document that stated she would undergo a procedure involving “Bilateral Replace Saline Smaller.” A preoperative AP photograph taken that same date by Clayman Practice staff demonstrates asymmetry, with the right implant smaller than the left. The left implant appears grossly overfilled.

53. In his operative report dated April 30, 2015, Clayman Senior diagnosed her as having a “Right Deflation” for which she was undergoing a “Bi-lateral Re-augmentation saline implant.” He documented that upon dissecting down to right breast implant capsule, the implant was found to have a “partial deflation with tissue in and around the valve.” The right implant was found to be intact. Nevertheless, both implants were removed and replaced with Allergan Natrelle Style 68 Medium Profile 360cc saline breast implants. Clayman Junior failed to document how much saline he used to inflate the implants, and he merely documented that they were “Inflated to their optimal capacity to minimize rippling and give the patient her desired look with as much symmetry as possible without added scars.” According to the OR Record, the entire procedure took 99 minutes to complete.

54. On May 14, 2015, Ms. Bianchi returned to have the sutures at her incision sites removed. At that time she reported to Clayman Junior that her breast implants were still too large. Again, Clayman Junior told her that she would “love them.” On or between April 30, 2015, and May 14, 2015, Clayman Junior had Ms. Bianchi sign an Allergan Warranty claim form stating that her right breast implant was ruptured, deflated, or leaking. Ms. Bianchi was

never aware that what she was signing was Allergan's warranty application. She reports that she was always presented with blank forms to sign, and was told that they would be filled out later.

55. On April 1, 2016, Ms. Bianchi returned to Clayman Junior and reported that her right breast had been hurting for three months, and that her breasts were still too large. In his progress note for that date, Clayman Junior documented that she denied any trauma or injury, and he noted she had no evidence of capsular contracture. He further documented that she wanted her breasts to be smaller, and he recommended that undergo a procedure in which he decreased the volume of her implants. Mark A. Clayman failed to provide Ms. Bianchi with a surgical estimate.

56. On May 6, 2016, Ms. Bianchi presented to the Clayman Practice for her fourth breast surgery with Clayman Junior. In the surgical intake paperwork, she wrote that her breasts were "too large," and that she wanted them to be smaller and not sag. Before the procedure, Clayman Practice personnel had her sign an informed consent document that stated she would undergo a "Bilateral Breast Adjustment decrease of saline implants" procedure involving "Bilateral Replace Saline Smaller." A preoperative AP photograph taken that same date by Clayman Practice staff demonstrates that neither of Ms. Bianchi's breast implants had a leak, rupture or deflation, and that her breasts were too large relative to the size of her body; her implants were grossly overfilled, with apparent flattening of the breast mounds.

57. In the operative report dated May 6, 2016, Clayman Junior documented initially removing 150cc from each breast implant, but that he re-inflated the breasts with 75cc for a net reduction of 75cc in each breast. He further documented that she then had Allergan Natrelle

Style 68 Medium Profile 360cc implants that were each inflated with 400cc of saline.¹³
According to the OR Record, the entire procedure took 42 minutes to complete.

58. Ms. Bianchi reports that she has continuously experienced pain in both breasts since her last surgery with Clayman Junior.

COUNT I – CLAYMAN DEFENDANTS’ MEDICAL NEGLIGENCE

59. Ms. Bianchi re-alleges and incorporates by reference paragraphs 1 through 58.

60. At all times material, Clayman Junior owed Ms. Bianchi a duty to exercise that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, was recognized as acceptable and appropriate by reasonably careful physicians caring for a patient such as Ms. Bianchi.

61. On or between November 19, 2013, and May 25, 2016, Clayman Junior and/or the Clayman Practice fell below the accepted and/or applicable standard of care in the treatment of Ms. Bianchi in one or more of the following ways:

a. Failing to properly document Ms. Bianchi’s medical and surgical care. Clayman Junior’s medical documentation for this patient is far below standard of care. There is no detailed documentation of specific patient complaints, physical examinations, or explanation of medical decision making for any patient encounter. The patient photographs consist of single AP photographs, each taken in a different setting and from a different angle/distance. These photographs are below standard of care, which would include consistent 5 view photographs (AP, left and right oblique, and left and right lateral) before and after each surgery, and at long term follow up.

¹³ Her subsequent plastic surgeon documented that her implants had actually been inflated to at least 600cc each.

b. Failing to listen to the reasonable requests of the patient. It is clear that Clayman Junior ignored his patient's request to maintain her implant size of 275cc. At each operation, he left her with larger implants than she requested. This resulted in further stretching of her skin, further atrophy of the overlying breast tissue, further deformity, and pain. It is negligent to continually ignore a patient's highly specific and reasonable requests to replace her implants with the exact same size implants;

c. Repeatedly misrepresenting the patient's physical condition and anatomy to her as a justification for problems caused by his surgical decisions. In the operative notes, Clayman Junior repeatedly remarks that the patient has a pectus deformity with rib asymmetries, which he repeatedly used as a justification for her persistent asymmetry, deflecting any blame away from himself. Yet, these remarks were false and misleading, as the pectus deformity with rib asymmetries is not apparent any of the photographs, and no other physicians have advised her of such both before and after she was under the care of Clayman Junior;

d. Failing to consider and/or perform a mastopexy, as opposed to replacing her existing implants with grossly overfilled saline implants. In her medical records, Clayman Junior repeatedly misrepresents that she refused "further anchor scars." This is nonsensical as she already had anchor scars from a prior mastopexy. Ms. Bianchi states he never discussed the potential for a mastopexy during her initial visits with him, and that they only discussed mastopexies much later in her care. When she asked him about a mastopexy, Clayman Junior told her that he does not perform mastopexies, and that the "internal lift" would achieve her goals. There is no recognized procedure called an "internal lift." When Clayman Junior refers to an "internal lift," he actually means that

he will be placing grossly overfilled saline implants into the breasts; sometimes, he also administers internal sutures even though they cannot accomplish external lifting of the breasts. “Internal lifts” predispose women to painful areas of hard scar tissue, asymmetries, and capsular contracture, all of which he later uses as justification for making warranty claims to Allergan. Ms. Bianchi would have benefited from an exchange to comparable or smaller sized implants, with a mastopexy to re-drape her breast skin and tissue over the implants. Clayman Junior chooses the “internal lift” over mastopexies because doing so is quicker and easier for him, albeit at the expense of the patient’s best interests;

e. Repeatedly providing medically unnecessary and ineffective care. Clayman Junior repeatedly gave Ms. Bianchi vitamin B12 injections in the clinic for unknown reasons. There is no medical justification for giving B12 injections to a patient recovering from breast augmentation surgery, nor is doing so part of any medically accepted treatment protocol for breast augmentation surgery;

f. By repeatedly, grossly overfilling Ms. Bianchi’s breast implants, which predisposed her to potential leakage due to valve failure and nullified the terms of the Allergan warranties. This resulted in further deformities at her breasts, which progressively became more difficult and expensive to surgically correct;

g. By failing to perform revision breast augmentation procedures with appropriately sized, silicone gel filled implants, a proper site change to a submuscular plane, an inframammary approach, and proper anesthesia with some level of muscle paralysis, which would have more likely than not have resulted in an acceptable aesthetic outcome and resolution of Ms. Bianchi’s complaints;

h. By failing to use an appropriate type and quality of anesthesia for Ms. Bianchi's first procedure with him, as well as in the subsequent removal and replacement procedures. Clayman Junior used the sedation protocol of ketamine and versed, which was administered by a registered nurse and not a certified registered nurse anesthetist (CRNA). This is significant, as the difference between a CRNA and a registered nurse is the ability to manage an airway during the procedure. The lack of presence of someone who is trained to manage an airway under sedation leads to significant under-sedation. In this case the patient was under-sedated for the initial procedure and all subsequent removal and replacement surgeries. Intravenous sedation should be deep enough to adequately perform the procedure without the patient waking up during the procedure or experiencing intraoperative pain;

i. By failing to appropriately assess and counsel Ms. Bianchi about realistic and safe recommendations that would address her concerns and obtain her goals. Ms. Sweat-Cole's complaints and persistent deformities were set in motion by a combination of poor preoperative counseling and assessment, as well as poor to non-existent surgical planning and preparation, and poor intraoperative execution of the first surgery and all subsequent surgeries. Initially, a properly executed dual plane breast augmentation with appropriately sized silicone gel-filled implants would have more likely than not to have delivered the aesthetic result she desired. Instead, she was left with a continuing deformity and poor aesthetic appearance that included overfilled saline implants in a subglandular position, breast size asymmetry, and position asymmetry;

j. By failing to take measures to prevent infectious agents and other materials from contaminating her implants; and/or

k. On one or more occasions, by fraudulently concealing or intentionally misrepresenting to Ms. Bianchi and others that her saline implant spontaneously deflated as a result of defects in the implants rather than due to his surgical practices. Such fraud, concealment, or intentional misrepresentation caused Ms. Bianchi to conclude that the problems she was having with her breasts were the result of product defects rather than her surgeon's breaches of the applicable standard of care.

62. As a direct and proximate result of above noted breach or breaches of the standard of care by Clayman Junior and/or the Clayman Practice, Ms. Bianchi suffered bodily injury and resulting pain and suffering, mental anguish, disability, disfigurement, and loss of the capacity for the enjoyment of life, has incurred and will incur in the future expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. These losses are permanent or continuing in nature, and she will suffer them in the future.

63. Furthermore, on one or more occasions Clayman Junior and/or employees or agents of the Clayman Practice fraudulently concealed or intentionally misrepresented to Ms. Bianchi and/or others that a saline implant that had been implanted in her body spontaneously deflated, ruptured, or leaked as a result of a product defect rather than breaches of the standard of care; such fraud, concealment, or intentional misrepresentation caused Ms. Bianchi to conclude that the problems she was having with her breasts were the result of product defects rather than the result of breaches of the applicable standard of care by Clayman Junior and/or employees or agents of the Clayman Practice.

WHEREFORE, the Plaintiff, **CATHERINE BIANCHI**, demands judgment for damages against the Defendants, **MARK A. CLAYMAN, M.D.** and **LOREN Z. CLAYMAN, M.D., P.A.** together with the costs of this action, and the Plaintiff respectfully demands a trial by jury

on all issues so triable.

COUNT II – CLAYMAN DEFENDANTS' BREACH OF FIDUCIARY DUTY

64. Ms. Bianchi re-alleges and incorporates by reference paragraphs 1 through 58.

65. On or between November 19, 2013 and May 25, 2016, Ms. Bianchi was a patient of Clayman Junior and the Clayman Practice. By virtue of the physician-patient relationship, Clayman Junior and the Clayman Practice had a fiduciary duty to Ms. Bianchi to not perform acts for his/its own pecuniary gain that were contrary to her welfare.

66. Clayman Junior and/or the Clayman Practice violated this fiduciary duty to Ms. Bianchi in one or more of the following ways:

(a). By repeatedly claiming that one of her breast implants had spontaneously deflated as a result of a product defect when in fact it had not.

(b). By repeatedly operating on Ms. Bianchi, which placed her at an increased risk for surgical and anesthetic complications, yet simply repeating the same procedures that were previously performed.

(c). By repeatedly not performing the surgery that her physical condition actually required in favor of surgery that took less time and skill, to save Clayman Junior and/or the Clayman Practice time and money.

(d). By repeatedly operating on her when he/it knew or should have known that he/it did not have the skill or competency to perform the surgeries within the standard of care.

(e). By repeatedly operating on her so that Clayman Junior and/or the Clayman Practice could recover a surgical fee from Allergan each time.

(f). By performing surgery with inadequate anesthesia because it was cheaper, which in turn led to improper implant placement, as well as increased pain, discomfort, and anxiety.

67. Furthermore, on one or more occasions Clayman Junior and/or employees or agents of the Clayman Practice fraudulently concealed or intentionally misrepresented to Ms. Bianchi and/or to others that a saline implant that had been implanted in her body spontaneously ruptured, deflated or leaked as a result of a product defect, when it had not; such fraud, concealment, or intentional misrepresentation caused Ms. Bianchi to conclude that the problems she was having with her breasts were the result of product defects rather than the result of breaches of the applicable standard of care by Clayman Junior and/or employees or agents of the Clayman Practice.

WHEREFORE, the Plaintiff, **CATHERINE BIANCHI**, demands judgment for damages against the Defendants, **MARK A. CLAYMAN, M.D.** and **LOREN Z. CLAYMAN, M.D., P.A.** together with the costs of this action, and the Plaintiff respectfully demands a trial by jury on all issues so triable.

COUNT III – CLAYMAN DEFENDANTS' FRAUD

68. Ms. Bianchi re-alleges and incorporates by reference paragraphs 1 through 58.

69. On one or more occasions, Clayman Junior and/or employees or agents of the Clayman Practice made the following false statements or representations, which were intended to conceal his/its inability or unwillingness to perform the breast augmentation procedures competently and within the standard of care, and which in fact misled Bianchi and/or caused her to respond in the following ways to her detriment:

a. On or about November 19, 2013, Clayman Junior told Ms. Bianchi that he

would give her a special rate of \$3,750 for a breast augmentation changeout procedure and “internal lift” compared to his normal rate of \$7,200. In fact, \$3,750 was his usual and customary rate for this procedure, as opposed to \$7,200; also, there is no recognized procedure known as an “internal lift.” One or both of these representations caused Ms. Bianchi to conclude that she was getting a special rate for the proposed surgery, and that the proposed surgery would involve a procedure known as an “internal lift.” As a result, she proceeded with the surgery recommended by Clayman Junior instead of going to another plastic surgeon;

b. On or about December 19, 2013, employees or agents of the Clayman Practice had Ms. Bianchi sign a surgical consent form stating that she would be undergoing an “internal lift” procedure. In fact, there is no recognized breast augmentation procedure called an “internal lift.” This representation caused Ms. Bianchi to believe there was a breast augmentation procedure known as an “internal lift.” As a result, Ms. Bianchi agreed to undergo the surgery recommended by Clayman Junior instead of going to a different plastic surgeon.

c. On or about November 6, 2014, Clayman Junior told Ms. Bianchi that she probably had a spontaneous rupture, leak, or deflation at her left breast implant as a result of a product defect and that she needed to have both of her breast implants removed and replaced. In fact, she did not have a rupture, leak or deflation at either of her breast implants due to a product defect. This representation caused Ms. Bianchi to conclude that the problems she was experiencing with her breasts were not the result of breaches of the standard of care by Clayman Junior and/or employees or agents of the Clayman Practice in the previous surgery, but that she had a defective left breast implant. This

representation caused Ms. Bianchi to agree to have another surgery performed by Clayman Junior, and, as a result, she did not seek a second opinion from another plastic surgeon, nor did she seek legal advice for a potential medical negligence claim.

d. On or about November 21, 2014, Clayman Junior and/or employees or agents of the Clayman Practice sent Allergan a warranty claim form stating that her left breast implant was ruptured, leaking or deflated as a result of a product defect. In fact, Ms. Bianchi did not have a spontaneous rupture, leak or deflation of her left breast implant as a result of a product defect. This representation caused Ms. Bianchi and/or others to conclude that she had a rupture, leak, or deflation at her left implant as a result of a product defect as opposed to due to a breach of the standard of care by Clayman Junior. As a result, Ms. Bianchi did not seek a second opinion from another plastic surgeon, nor did she seek legal advice for a potential medical negligence claim.

e. On or about February 9, 2015, Clayman Junior told Ms. Bianchi that he would perform a procedure to decrease the volume of saline in her breast implants. In fact, he intended to pursue the same breast implant warranty scheme that he and Clayman Senior had followed thousands of times before, whereby he falsely claimed that the patient experienced a spontaneous rupture, leak or deflation as a result of a product defect, and for which he made a warranty claim in order to receive payment of either \$1,200 or \$2,400 from Allergan. This representation caused Ms. Bianchi to conclude that there was no reason to seek a second opinion from another plastic surgeon or to seek legal advice for a potential medical negligence claim. As a result, she agreed to have another surgery by Clayman Junior rather than seek a second opinion from another plastic surgeon or seek legal advice for a potential medical negligence claim.

f. On or about February 9, 2015, Clayman Junior provided Ms. Bianchi with a written surgical estimate that stated he was going to perform a procedure to decrease the volume of saline in her breast implants. In fact, he intended to pursue the same breast implant warranty scheme that he and Clayman Senior had followed thousands of times before, whereby he falsely claimed that the patient experienced a spontaneous rupture, leak or deflation as a result of a product defect, and for which he made a warranty claim in order to receive payment of either \$1,200 or \$2,400 from Allergan. This representation caused Ms. Bianchi to conclude that there was no reason to seek a second opinion from another plastic surgeon or to seek legal advice for a potential medical negligence claim. As a result, she agreed to have another surgery by Clayman Junior rather than seek a second opinion from another plastic surgeon or seek legal advice for a potential medical negligence claim.

g. On or between April 30, 2015 and May 14, 2015, Clayman Junior had Ms. Bianchi sign a warranty claim form stating that she had a spontaneous deflation as a result of a rupture, leak, or deflation due to a product defect. In fact, she did not have a spontaneous rupture, leak, or deflation as a result of a product defect. This representation caused Ms. Bianchi and/or others to conclude that she experienced a spontaneous rupture, leak, or deflation as a result of a product defect, as opposed to due to a breach of the standard of care by Clayman Junior. As a result, Ms. Bianchi did not seek a second opinion from another plastic surgeon or seek legal advice for a potential medical negligence claim.

70. As a result of the above false statements or representations, Clayman Junior and and/or the Clayman Practice were able to continue collecting money in relation to the medical

and surgical care of Ms. Bianchi, Ms. Bianchi did not seek a second opinion from another plastic surgeon, and/or Ms. Bianchi delayed seeking legal counsel for potential medical negligence.

71. As a direct and proximate result of the above noted false statements or representations of Clayman Junior and/or employees or agents of the Clayman Practice, Ms. Bianchi suffered bodily injury and resulting pain and suffering, mental anguish, disability, disfigurement, and loss of the capacity for the enjoyment of life, has incurred and will incur in the future expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. These losses are permanent or continuing in nature, and she will suffer them in the future.

WHEREFORE, the Plaintiff, **CATHERINE BIANCHI**, demands judgment for damages against the Defendants, **MARK A. CLAYMAN, M.D.** and **LOREN Z. CLAYMAN, M.D., P.A.** together with the costs of this action, and the Plaintiff respectfully demands a trial by jury on all issues so triable.

**COUNT IV – CLAYMAN DEFENDANTS’ AND ALLERGAN’S CONSPIRACY TO
COMMIT BREACH OF FIDUCIARY DUTY AND/OR FRAUD**

72. Ms. Bianchi re-alleges and incorporates by reference paragraphs 1 through 58, 66, 67, 69, and 70.

73. On or before November 19, 2013, Clayman Junior, the Clayman Practice, and/or Elana Clayman entered into an agreement with Allergan to commit one or more breaches of a fiduciary duty and/or fraud in relation to the patients of the Clayman practice. The following acts and conduct are illustrative of the parties’ intent to enter this agreement:

a. The Claymans sending removed breast implants and warranty claim paperwork to Allergan, signed by both the patient and Clayman Junior, stating that the

patient had a spontaneous rupture, deflation, or leak as a result of a product defect that required a removal and replacement surgery, and assigning the benefits of the warranty claim to the Claymans;

b. Allergan sending the Claymans a check for the Surgery Money despite the fact that its “Laboratory Analysis” on the returned breast implants found no evidence of a loss of shell integrity, resulting in implant rupture or deflation;

c. Allergan further demonstrating its assent to the agreement by repeating its conduct (paying warranty claims for saline breast implants that Allergan knew did not demonstrate a loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention) at least 3,045 times before January 1, 2013;

d. Allergan receiving, as consideration for its payment of the Surgery Money, the Claymans’ purchase of large quantities of breast implants, medical devices, and pharmaceuticals from Allergan.

74. Allergan, through its employees or agents, knew that Clayman Junior and/or the Clayman Practice were breaching a fiduciary duty owed to Ms. Bianchi, and/or committing fraud upon her as well, due to the following:

(a). At the time that Allergan paid the warranty claim in relation to the November 21, 2014 implant removal and replacement surgery, Allergan had received more than 3,843 warranty claims from the Clayman Practice for saline breast implants that Allergan knew did not demonstrate a “loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention”;

(b). Allergan’s *Laboratory Analysis* report for the left saline filled breast implant that was implanted by Clayman Junior into Ms. Bianchi on December 9, 2013,

and explanted by Clayman Junior on November 21, 2014, did not demonstrate a “loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention,” and, thus, the November 21, 2014 surgery was not necessary as a result of a failed breast implant;

(c). The rate of ruptures, deflations, or leaks of Natrelle saline filled implants claimed by the Clayman Practice was markedly higher than the rate shown by Allergan’s own studies for Natrelle saline filled implants.

75. Allergan committed one or more of the following overt acts in furtherance of the conspiracy to breach a fiduciary duty and/or to commit fraud:

(a). Continuing to sell saline breast implants to the Claymans after 2012, even though Allergan had already received more than 3,045 warranty claims from the Clayman Practice for saline breast implants that Allergan knew did not demonstrate a “loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention”;

(b). Paying the Clayman Practice’s warranty claim, without requesting further corroboration, in relation to the left saline breast implant that Clayman Junior placed into Ms. Bianchi on December 9, 2013, and which Clayman Junior surgically removed on November 21, 2014;

(c). Paying the Clayman Practice’s warranty claim in relation to the left saline breast implant that Clayman Junior placed into Ms. Bianchi on December 9, 2013, and which Clayman Junior surgically removed on November 21, 2014, even though Allergan had already received more than 3,843 warranty claims from the Clayman Practice knew

did not demonstrate a loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention; and/or

(d). Continuing to sell saline breast implants to the Clayman Practice after 2014, even though Allergan had already received more than 3,843 warranty claims for saline breast implants from the Clayman Practice that Allergan knew did not demonstrate a “loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention.

76. On or before November 21, 2014, through her work as the office manager of the Clayman Practice, Elana Clayman knew that Clayman Junior and/or the Clayman Practice were breaching a fiduciary duty owed to Ms. Bianchi, and/or committing fraud upon her as well, due to the following:

a. The rate of ruptures, deflations, or leaks of Natrelle saline filled implants claimed by the Clayman Practice was markedly higher than the rates of ruptures, deflations, or leaks that saline breast implants typically experience for a similar number of patients;

b. The Clayman Practice’s warranty claims to Allergan were fraudulent because they were for saline breast implants that had not actually experienced ruptures, deflations, or leaks; and

c. The Clayman Practice’s breast implant patients were undergoing breast implant revision surgeries that were not necessary as a result of ruptures, deflations, or leaks of their saline breast implants.

77. On or between November 19, 2013, and May 6, 2016, Elana Clayman committed one or more of the following overt acts in furtherance of the conspiracy to breach a fiduciary

duty and/or to commit fraud:

- a. depositing the Surgery Money received from Allergan into a separate bank account or accounts controlled in whole or in part by Elana Clayman;
- b. managing the accounting of the separate bank account or accounts that held the Surgery Money in separate bookkeeping ledgers or systems controlled in whole or in part by Elana Clayman; and/or
- c. managing the Surgery Money separately from other income received by the Clayman Practice so that the Surgery Money would not be treated as taxable income by the Internal Revenue Service, the Florida Department of Revenue, or any other governmental agency.

78. As a direct and proximate result of the above noted conspiracy to commit fraud and/or breach of fiduciary duty by Clayman Junior, the Clayman Practice, Elana Clayman, and Allergan, Ms. Bianchi suffered bodily injury and resulting pain and suffering, mental anguish, disability, disfigurement, and loss of the capacity for the enjoyment of life, has incurred and will incur in the future expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. These losses are permanent or continuing in nature, and she will suffer them in the future.

79. Furthermore, as a direct and proximate result of the above noted conspiracy to breach a fiduciary duty and/or to commit fraud by Clayman Junior, the Clayman Practice, Elana Clayman, and Allergan, Ms. Bianchi has spent monies in the amount of \$3,750 or more, for medical and/or surgical care by the Clayman Practice that was of no value, and which has caused her to have to incur future medical expenses to correct the damages done by said medical and/or surgical care.

WHEREFORE, the Plaintiff, **CATHERINE BIANCHI**, demands judgment for compensatory damages against the Defendants, **MARK A. CLAYMAN, M.D., LOREN Z. CLAYMAN, M.D., P.A., ELANA CLAYMAN**, and **ALLERGAN SALES, LLC**, together with the costs of this action, and the Plaintiff respectfully demands a trial by jury on all issues so triable.

**ALLERGAN AND ELANA CLAYMAN AIDING AND ABETTING THE
CLAYMAN PRACTICE'S BREACH OF FIDUCIARY DUTY AND/OR FRAUD**

80. Ms. Bianchi re-alleges and incorporates by reference paragraphs 1 through 58, 66, 67, 69, and 70.

81. Allergan, through its employees or agents, knew that Clayman Junior and/or the Clayman Practice was/were breaching a fiduciary duty owed to Ms. Bianchi, and/or committing fraud upon her as well, due to the following:

(a). At the time that Allergan paid the warranty claim in relation to the November 21, 2014 implant removal and replacement surgery, Allergan had received more than 3,843 previous warranty claims from the Clayman Practice for saline breast implants that Allergan knew did not demonstrate a “loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention”;

(b). Allergan’s *Laboratory Analysis* report for the left saline filled breast implant that that was surgically removed from her by Clayman Junior on November 21, 2014, did not demonstrate a “loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention,” and, thus, the November 21, 2014 surgery was not necessary as a result of a failed breast implant; and

(c). By November 21, 2014, the rate of ruptures, deflations, or leaks for patients with Natrelle saline filled implants claimed by the Clayman Practice was markedly higher than the rate shown by Allergan's own studies for Natrelle saline filled implants.

82. Despite the aforesaid knowledge of Allergan through its employees or agents, Allergan provided substantial assistance to Clayman Junior and/or the Clayman Practice in committing fraud against, and/or breaching a fiduciary duty owed to, Ms. Bianchi in one or more of the following ways:

(a). Continuing to sell saline breast implants to the Claymans after 2012, even after Allergan had already received more than 3,045 warranty claims from the Clayman Practice for saline breast implants that Allergan knew did not demonstrate a "loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention";

(b). Paying the warranty claim of the Clayman Practice and/or Clayman Junior, without requesting further corroboration, in relation to the left filled breast implant that Clayman Junior placed into Ms. Bianchi on December 9, 2013, and which Clayman Junior surgically removed on November 21, 2014; and

(c). Paying the Clayman Practice's warranty claim in relation to the left saline breast implant that Clayman Junior placed into Ms. Bianchi on December 9, 2013, and which Clayman Junior surgically removed on November 21, 2014, even though Allergan had already received more than 3,843 warranty claims from the Clayman Practice that Allergan knew did not demonstrate a loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention

(d). Continuing to sell saline breast implants to the Clayman Practice after

2014 even though Allergan had already received more than 4,900 warranty claims for saline breast implants from the Clayman Practice that Allergan knew did not demonstrate a “loss of shell integrity, resulting in implant rupture or deflation that requires surgical intervention.

83. On or before November 21, 2014, through her work as the office manager of the Clayman Practice, Elana Clayman knew that Clayman Junior and/or the Clayman Practice were breaching a fiduciary duty owed to Ms. Bianchi, and/or committing fraud upon her as well, due to the following:

- a. The rate of ruptures, deflations, or leaks of Natrelle saline filled implants claimed by the Clayman Practice was markedly higher than the rates of ruptures, deflations, or leaks that saline breast implants typically experience for a similar number of patients;

- b. The Clayman Practice’s warranty claims to Allergan were fraudulent because they were for saline breast implants that had not actually experienced ruptures, deflations, or leaks; and

- c. The Clayman Practice’s breast implant patients were undergoing breast implant revision surgeries that were not necessary as a result of ruptures, deflations, or leaks of their saline breast implants.

84. On or between November 19, 2013, and May 6, 2016, Elana Clayman committed one or more of the following overt acts in furtherance of the conspiracy to breach a fiduciary duty and/or to commit fraud:

- a. depositing the Surgery Money received from Allergan into a separate bank account or accounts controlled in whole or in part by Elana Clayman;

b. managing the accounting of the separate bank account or accounts that held the Surgery Money in separate bookkeeping ledgers or systems controlled in whole or in part by Elana Clayman; and/or

c. managing the Surgery Money separately from other income received by the Clayman Practice so that the Surgery Money would not be treated as taxable income by the Internal Revenue Service, the Florida Department of Revenue, or any other governmental agency.

85. As a direct and proximate result of the substantial assistance provided by Allergan and Elana Clayman to Clayman Junior and/or the Clayman Practice, Ms. Bianchi suffered bodily injury and resulting pain and suffering, mental anguish, disability, disfigurement, and loss of the capacity for the enjoyment of life, has incurred and will incur in the future expense of hospitalization, medical and nursing care and treatment, and aggravation of a previously existing condition. These losses are permanent or continuing in nature, and she will suffer them in the future.

86. Furthermore, as a direct and proximate result of the above noted substantial assistance provided by Allergan and Elana Clayman to Claymans Junior and/or the Clayman Practice, Ms. Bianchi has spent monies in the amount of \$3,750 or more, for medical and/or surgical care by the Clayman Practice that was of no value, and which has caused her to have to incur future medical expenses in the future to correct the damages done by said medical and/or surgical care.

WHEREFORE, the Plaintiff, **CATHERINE BIANCHI**, demands judgment for compensatory damages against the Defendants, **MARK A. CLAYMAN, M.D., LOREN Z. CLAYMAN, M.D., P.A., ELANA CLAYMAN** and **ALLERGAN SALES, LLC**, together

with the costs of this action, and the Plaintiff respectfully demands a trial by jury on all issues so triable.

/s/ Christopher Shakib
Christopher Shakib, Esquire
TERRELL HOGAN & YEGELWEL, P.A.
233 East Bay Street, 8th Floor
Jacksonville, Florida 32202
Telephone: (904) 632-2424
Facsimile: (904) 632-5049
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Secondary Email: jfleury@terrellhogan.com
Florida Bar No.: 0947865
Attorney for the Plaintiffs

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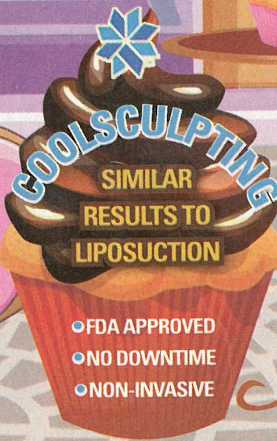
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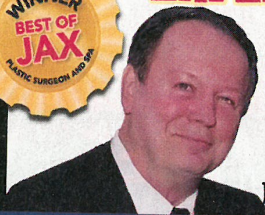


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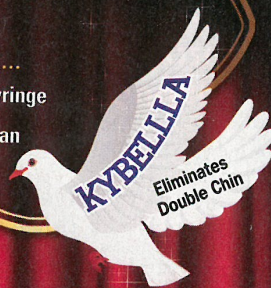
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